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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DEWEN QIU, ZHONG-MIN WEI,
and STEVEN V. BEER

Appeal 2009-001904
Application 09/766,348
Technology Center 1600

Decided:[1] August 3, 2009

Before TONI R. SCHEINER, ERIC GRIMES, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* FREDMAN.

Opinion Dissenting filed by *Administrative Patent Judge* GRIMES.

FREDMAN, *Administrative Patent Judge*.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of imparting pathogen resistance to plants, by expressing a hypersensitive response elicitor polypeptide, or harpin, in transgenic plants. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

The Claims

Claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84 are on appeal. We will focus on claims 41, 61 and 75, which are representative and read as follows:

> 41. A method of imparting pathogen resistance to plants, the method comprising:
>
> providing a transgenic plant seed transformed with a transgene comprising a DNA molecule encoding a hypersensitive response elicitor polypeptide or protein comprising an amino acid sequence of SEQ ID NO:l, SEQ ID NO:3, SEQ ID NO:5, or SEQ ID NO:7 and a promoter that is not pathogen-inducible, the promoter being operatively coupled to the DNA molecule encoding the hypersensitive response elicitor polypeptide or protein;
>
> planting the transgenic plant seed in soil; and
>
> propagating a plant from the planted seed, whereby expression of the hypersensitive response elicitor polypeptide or protein by the plant imparts systemic pathogen resistance to the plant.
>
> 61. A method of imparting pathogen resistance to plants, the method comprising:
>
> transforming a plant with a transgene comprising a DNA molecule encoding a hypersensitive response elicitor polypeptide or protein comprising an amino acid sequence of SEQ ID NO:l, SEQ ID NO:3, SEQ ID NO:5, or SEQ ID NO:7 and a promoter that is not pathogen-inducible, the

promoter being operatively coupled to the DNA molecule encoding the hypersensitive response elicitor polypeptide or protein, whereby said transforming provides for expression of the hypersensitive response elicitor polypeptide or protein that imparts systemic pathogen resistance to the plant.

75. A transgenic plant produced by a process comprising: transforming a plant with a transgene comprising a DNA molecule encoding a hypersensitive response elicitor polypeptide or protein comprising an amino acid sequence of SEQ ID NO:l, SEQ ID NO:3, SEQ ID NO:5, or SEQ ID NO:7 and a promoter that is not pathogen-inducible, the promoter being operatively coupled to the DNA molecule encoding the hypersensitive response elicitor polypeptide or protein, whereby said transforming provides for expression of the hypersensitive response elicitor polypeptide or protein to impart systemic pathogen resistance to the transgenic plant.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Bauer et al.	US 5,850,015	Dec. 15, 1998
Beer et al.	US 6,174,717 B1	Jan. 16, 2001

Tampakaki et al., *Elicitation of Hypersensitive Cell Death by Extracellularly Targeted $HrpZ_{psph}$ Produced in Planta*, 13 MOLECULAR PLANT-MICROBE INTERACTIONS 1366-1374 (2000).

The issues

A. The Examiner rejected claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Ans. 3-4).

B. The Examiner rejected claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84 under 35 U.S.C. § 112, first paragraph as lacking enablement (Ans. 4-7).

A. 35 U.S.C. § 112, first paragraph - written description requirement

The Examiner finds that

> Neither the instant specification nor the originally filed claims appear to provide support for recitation of a "promoter that is not pathogen-inducible" in claims 41, 61 and 75, line 5. The only reference to plant promoters in the specification, on pg 36, line 19, states "various promoters including pathogen-induced promoters".

(Ans. 3.)

Appellants contend that "[t]he clear meaning of [the Specification's] language is that 'various promoters' can be used to make the claimed transgenic plants" (App. Br. 6). Appellants contend that "[i]n the universe of 'various promoters' where 'pathogen- induced promoters' are an example, the rest of that universe of 'various promoters' must, as a simple matter of logic, be the claimed non-pathogen-inducible promoters" (App. Br. 6). Appellants contend that "[t]his is entirely consistent with the knowledge that those skilled in the art of transgenic plants would have possessed at the time the present invention was made" (App. Br. 6).

In view of these conflicting positions, we frame the written description issue before us as follows:

Did the Examiner err in finding that the disclosure of the Specification failed to demonstrate possession and descriptive support for a "promoter that is not pathogen-inducible?"

Findings of Fact (FF)

1. The Specification teaches that "[a]s is conventional in the art, such transgenic plants would contain suitable vectors with various promoters including pathogen-induced promoters, and other components needed for transformation, transcription, and possibly, translation" (Spec. 36, ll. 17-21).

2. The Specification teaches regarding procaryotic expression that "[p]romoters vary in their 'strength' (i.e. their ability to promote transcription). For the purposes of expressing a cloned gene, it is desirable to use strong promoters in order to obtain a high level of transcription and, hence, expression of the gene" (Spec. 32, ll. 12-16).

3. The Examiner finds that "the knowledge of those in skill in the art at the time of filing was that use of non-inducible promoters in expression of a harpin in a plant would kill the plant" (Ans. 4; *see, e.g.*, FF 11-15 below).

4. The Examiner finds that the "knowledge of the existence of constitutive promoters, i.e. promoters that are non-pathogen inducible, was such that one of skill in the art would expect that Applicant would have mentioned constitutive promoters if they were contemplated at the time of filing" (Ans. 4).

5. The Examiner finds that "[n]either the instant specification nor the originally filed claims appear to provide support for recitation of a 'promoter that is not pathogen-inducible' in claims 41, 61 and 75" (Ans. 3).

Principles of Law

It is the Examiner's "initial burden [to] present [ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a

description of the invention defined by the claims." *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976).

To satisfy the written description requirement, the inventor must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). "One shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

"Although [the inventor] does not have to describe exactly the subject matter claimed … the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

Analysis

A specific recitation of "a promoter that is not pathogen-inducible" was not disclosed *ipsis verbis* in the Specification (FF 5). Of course, *ipsis verbis* support is not required. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996).

The Examiner finds that "[p]romoters other than pathogen-induced ones as a class were not part of the originally filed invention" (Ans. 3). The reason given by the Examiner for why the skilled artisan would not find the Specification in possession of "a promoter that is not pathogen-inducible" is two fold. First, the Examiner finds that "the knowledge of those in skill in the art at the time of filing was that use of non-inducible promoters in expression of a harpin in a plant would kill the plant" (Ans. 4; FF 3).

Second, the Examiner finds that the "knowledge of the existence of constitutive promoters, i.e. promoters that are non-pathogen inducible, was such that one of skill in the art would expect that Applicant would have mentioned constitutive promoters if they were contemplated at the time of filing" (Ans. 4; FF 4).

The Specification does not reasonably appear to be in possession of "a promoter that is not pathogen-inducible" as required by claims 41, 61 and 75 (FF 1-4). "When no such description can be found in the specification, the only thing the PTO can reasonably be expected to do is to point out its nonexistence." *Hyatt v. Dudas*, 492 F.3d 1365, 1370 (Fed. Cir. 2007). "In the context of the written description requirement, an adequate prima facie case must therefore sufficiently explain to the applicant what … is missing from the written description." *Id.*

We are not persuaded by Appellants' argument that "[i]n the universe of 'various promoters' where 'pathogen- induced promoters' are an example, the rest of that universe of 'various promoters' must, as a simple matter of logic, be the claimed non-pathogen-inducible promoters" (App. Br. 6). Appellants further contend that "the phrase 'various promoters' in the specification would have been understood by those skilled in the art to encompass, besides pathogen-induced promoters, promoters that are *not* pathogen-inducible (e.g. constitutive promoters)" (App. Br. 6).

Appellants have set up a false dichotomy between constitutive promoters and pathogen induced promoters. As Takakura[2] discloses, there are dozens of different types of promoters beyond constitutive promoters,

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[2] Takakura et al., US 2004/0073970 A1, April 15, 2004.

including promoters which are induced "by physical or chemical stimulation, such as light, disease, injury or contact with an elicitor" (Takakura 3 ¶ 0024). Takakura teaches organ specific promoters which provide "specificity to an organ, such as a leaf, a root, a stem, a flower, a stamen and a pistil" (Takakura 3 ¶ 0025). Takakura teaches phase specific promoters which transcribe genes in "a phase, such as an initial, middle, and later growth phase" (Takakura 4 ¶ 0026). Not only does Appellants Specification not describe constitutive promoters, it also fails to discuss any of these other types of promoters, as well.

In *Gentry Gallery* the issue was whether the written description, which described a specific location of a control console on a reclining sofa, adequately supported broad claims that were not limited to this location of the console; the court found that "the scope of the right to exclude may be limited by a narrow disclosure." *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). In accord is *Curtis*, which notes "[a]s our reading of *In re Smythe* demonstrates, a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when, as is the case here, the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004).

The same analysis applies here, where the Specification describes a single category of promoters, pathogen-induced promoters, which function to express the hypersensitive response elicitor protein in plants (FF 2). The Specification does not describe other types of promoters and the Examiner

has provided specific reasoning as to why the skilled artisan, familiar with the prior art of Bauer and Beer would not expect the promoters to encompass non-pathogen inducible promoters such as constitutive promoters (FF 4-5). The numerous references cited by Appellants which teach the existence of constitutive promoters do not address the Examiner's point, which is that the skilled artisan would not have expected success in expression of the specific hypersensitive response elicitor protein in plants using constitutive promoters (FF 3). The skilled artisan would therefore not have recognized possession of non-pathogen inducible promoters in a disclosure which states "various promoters including pathogen-induced promoters" (FF 1, 3).

Conclusion of Law

The Examiner did not err in finding that the disclosure of the Specification failed to demonstrate possession and descriptive support for a "promoter that is not pathogen-inducible."

B. 35 U.S.C. § 112, first paragraph - enablement requirement

The Examiner finds that

> given the state of the art at the time of filing, one of skill in the art would not have expected a constitutive promoter to function in the instant invention because one of skill in the art would have expected expression in a plant of a harpin from a constitutive promoter to kill the plant.

(Ans. 6.)

Appellants contend that "[c]ompared to the knowledge at the time Bauer and Beer were filed, much more information was available regarding the constitutive expression of HR elicitors in plants at the time of the filing of the present application" (App. Br. 9). Appellants contend that "the use of

constitutive promoters and other non-pathogen-inducible promoters in transforming plants was well known in December 1997" (App. Br. 9). Appellants contend that "[t]he data shows that the constitutive expression of HrpN using the NOS promoter was not lethal to the transgenic plants, and that the transgenic plants exhibited pathogen resistance" (App. Br. 10).

In view of these conflicting positions, we frame the enablement issue before us as follows:

Did the Examiner err in finding that it would have required undue experimentation to express a hypersensitive response elicitor polypeptide with a "promoter that is not pathogen-inducible?"

Findings of Fact

Breadth of the Claims

6. The Examiner finds that the "claims are broadly drawn to a method of imparting pathogen resistance to plants by planting a seed transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor (harpin) of SEQ ID NO: 1, 3, 5, or 7 and a non-pathogen inducible promoter" (Ans. 4).

7. Claim 41 encompasses any promoters that are not "pathogen-inducible" (Claim 41).

Presence of Working Examples

8. The Examiner found that the "specification also does not teach any working examples in which a plant was transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor (harpin) of SEQ ID NO: 1, 3, 5, or 7 and a non-pathogen inducible promoter" (Ans. 6).

Amount of Direction or Guidance Presented

9. The Specification teaches that "transgenic plants transformed with a DNA molecule encoding a hypersensitive response elicitor polypeptide or protein are produced according to procedures well known in the art, such as biolistics or *Agrobacterium* mediated transformation" (Spec. 36, ll. 10-14).

10. The Examiner finds that the "instant specification makes no teaching as to the use of a constitutive promoter in expression of harpins in plants" (Ans. 6).

State of the Art and Unpredictability of the Art

11. Bauer was filed June 7, 1995. Bauer teaches that "[o]ne aspect of the present invention involves using the DNA molecule encoding the hypersensitive response elicitor from *Erwinia chrysanthemi* to transform plants in order to impart localized resistance to pathogens" (Bauer, col. 13, ll. 12-15).

12. Bauer teaches that

> Transformation of plants with the DNA molecule of the present invention is particularly useful where the plant does not exhibit a hypersensitive response to pathogens or is weakly responsive to such pathogens. This requires that $hrpN_{ech}$ be hooked up to the promoter of a plant gene that the pathogen induces such as PAL, CHS, etc. Otherwise, hrpN will kill the plant.

(Bauer, col. 13, ll. 21-27.)

13. Beer was originally filed July 1, 1992. Beer teaches that "another use [for harpin] would be the fusion of the gene encoding harpin to

specific promoters of plant genes to develop specific transgenic plants. When the plant gene is 'turned on', harpin would be expressed and the plant cell killed" (Beer, col. 24, ll. 9-12).

14. Beer teaches that

> Some appropriate plant gene promoters and their projected uses include genes involved in pollen development (resulting in the development of male sterile plants); genes that are expressed in response to infection by fungi . . . and genes involved in the development of senescence (to facilitate harvest, expression of hrp genes would result in defoliation).

(Beer, col. 24, ll. 13-22.)

15. Tampakaki was accepted for publication on August 9, 2000. Tampakaki teaches "[e]xpecting that endogenously produced harpin may be lethal to the plant, we used the tetracycline inducible (Tet) expression vector system to achieve conditional expression of the *hrpZ*$_{Psph}$ gene" (Tampakaki 1367, col. 1).

16. Koncz[3] (cited in Appellants' Evidence Appendix) represents a reference which teaches plant gene expression, and Koncz specifically teaches that "the expression of octopine and nopaline synthase genes is determined directly by their 5' upstream flanking sequences and is independent of the direct vincinity of the plant DNA sequences" (Koncz 1601-1602).

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[3] Koncz et al., *The opine synthase genes carried by Ti plasmids contain all signals necessary for expression in plants*, 2 EMBO JOURNAL 1597-1603 (1983).

17. The Wei Declaration teaches that "[i]n order to investigate whether transforming a plant or plant seed with a DNA molecule encoding a hypersensitive response elicitor[] results in specific plant responses, several transformation constructs containing the *hrpN* gene from *Erwinia amylovora* were generated" (Wei Dec. 08/11/04 ¶ 25).

18. The Wei Declaration teaches a construct with the NOS promoter and teaches that the "NOS promoter is considered a weak constitutive promoter and has been previously identified" (Wei Dec. 08/11/04 ¶ 26).

19. The Wei Declaration teaches that "plants grown from seeds harvested from plants transformed with a DNA molecule encoding the hypersensitive response elicitor HrpN from *Erwinia amylovora* exhibited enhanced disease resistance" (Wei Dec. 08/11/04 ¶ 28).

Principles of Law

"In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same ….' 35 U.S.C. § 112, para. 1." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005).

> Factors to be considered in determining whether a disclosure would require undue experimentation … include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

Analysis

> The Examiner concludes that
>
> > given the state of the art at the time of filing, one of skill in the art would not have expected a constitutive promoter to function in the instant invention because one of skill in the art would have expected expression in a plant of a harpin from a constitutive promoter to kill the plant.

(Ans. 6.) Based upon balancing the factors in the *Wands* analysis, we agree that undue experimentation would have been required to use the claimed invention. In particular, the teachings of Bauer, Beer and Tampakaki persuasively demonstrate that as of the time of filing, the skilled artisans expected expression of hypersensitive response elicitor polypeptides with constitutive promoters would be lethal to plants, and therefore ineffective in protecting the plants against pathogens.

We are not persuaded by Appellants' argument that Bauer and Beer "do not accurately represent the state of the art at the time of filing of the present invention" (App. Br. 9). Bauer was filed within five years of the instant Specification (FF 11). Beer was filed only two and one half years prior to Appellants' Specification (FF 13). Additionally, Tampakaki was

accepted for publication more than two years after Appellants' filing date and Tampakaki teaches "[e]xpecting that endogenously produced harpin may be lethal to the plant, we used the tetracycline inducible (Tet) expression vector system to achieve conditional expression of the $hrpZ_{Psph}$ gene" (Tampakaki 1367, col. 1; FF 15).

Appellants present no evidence that as of December 3, 1997, the filing date of the instant Specification, other skilled artisans differed from Bauer, Beer and Tampakaki in expecting that constitutive expression of hypersensitive response elicitor polypeptides would be lethal to plants (FF 11-15). *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

We are not persuaded by Appellants' citation of the Wei Declarations because these declarations do not establish that at the time of filing, the invention was enabled. *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003) ("Enablement is determined as of the effective filing date of the patent."). The Wei Declarations are dated February 3, 2003 and August 11, 2004. The August 11, 2004 Wei Declaration discusses successful experiments transforming plant seeds with hypersensitive response elicitors under the control of the weak constitutive NOS promoter (FF 17-19). The August 11, 2004 Wei Declaration does not, however, address the issue of enablement as of the filing date, but rather, shows evidence and experimental methods and procedures not found or disclosed in the Specification which were disclosed six years after Appellants' filing date. *See In re Glass*, 492 F.2d 1228, 1232 (CCPA 1974) ("If a disclosure is insufficient as of the time it is filed, can it be made

sufficient, while the application is still pending, by later publications which add to the knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention? We think it cannot. The sufficiency must be judged as of the filing date.")

In accord is *Monsanto*, where the Court noted that

> Monsanto's patent recites broad functional language in its claims. This court in *In re Goodman* addressed a very similar issue, holding the full scope of Goodman's patent not enabled due to an absence of reliable evidence of "gene transformation method of use with monocot plants" as of Goodman's 1985 filing date. 11 F.3d 1046, 1052 (Fed.Cir.1993). Again, in *Plant Genetic Systems*, this court held practicing stable gene transformation for monocot cells in 1987 required undue experimentation. 315 F.3d at 1338. As in these prior cases, the evidence here does not demonstrate that as of the filing date of the '835 patent (July 7, 1986) the invention was enabled.

Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1361, 1362 (Fed. Cir. 2007). Here too, the claim uses broad functional language to a "promoter that is not pathogen inducible" without any showing by Appellants of evidence of the existence of any such promoters in the prior art.

Conclusion of Law

The Examiner did not err in finding that it would have required undue experimentation to express a hypersensitive response elicitor polypeptide with a "promoter that is not pathogen-inducible."

SUMMARY

In summary, we affirm the rejection of claims 41, 61 and 75 under 35 U.S.C. § 112, first paragraph, written description. Pursuant to 37 C.F.R. §

41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 49-51, 53, 58-60, 69-71, 73, 76, 77, 80, 82, and 84.

We affirm the rejection of claims 41, 61 and 75 under 35 U.S.C. § 112, first paragraph, enablement. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 49-51, 53, 58-60, 69-71, 73, 76, 77, 80, 82, and 84.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

GRIMES, *Administrative Patent Judge*, dissenting.

I respectfully dissent from the affirmance of both the written description and nonenablement rejections. In my view, the evidence of record does not support affirming either rejection.

A. 35 U.S.C. § 112, first paragraph - written description requirement

The Specification states that

> transgenic plants transformed with a DNA molecule encoding a hypersensitive response elicitor polypeptide or protein are produced according to procedures well known in the art, such as biolistics or *Agrobacterium* mediated transformation. . . . As is conventional in the art, such transgenic plants would contain suitable vectors with various promoters including pathogen-induced promoters.

(Spec. 36: 10-19.)

I agree with Appellants that this passage from the Specification clearly describes two overlapping groups of promoters: "various promoters," or promoters generally, and "pathogen-induced promoters." Having described those groups, the Specification necessarily also describes the larger group minus the smaller; in other words, promoters that are not pathogen-inducible.

The majority faults Appellants' Specification for not discussing specific types of non-pathogen-inducible promoters, but the majority also cites Takakura's disclosure that numerous promoters were known in the art as of the effective filing date. Takakura provides examples of promoters that are functional in plants that are constitutive (Takakura 3, ¶ 23), inducible by various conditions (*id.* at 3, ¶ 24), organ-specific (*id.* at 3, ¶ 25), or phase-

specific (*id.* at 4, ¶ 26). Takakura cites eleven scientific publications disclosing these various promoters that were published in 1996 or before.

As the Federal Circuit recently summed up its case law,

> (1) examples are not necessary to support the adequacy of a written description[;] (2) the written description standard may be met . . . even whe[n] actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

Even more directly on point, the *Falkner* court held that where "accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences . . . , satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." *Id.* at 1368 (footnote omitted.) "Indeed, a requirement that [applicants] recite known DNA structures, if one existed, would serve no goal of the written description requirement." *Id.*

The Examiner's position – that the Specification describes only pathogen-induced promoters or promoters generally (Answer 3) – is a "'hypertechnical application' of the written description requirement" like that criticized in *In re Driscoll*, 562 F.2d 1245, 1249 (CCPA 1977). I would reverse the rejection for lack of adequate written description.

B. 35 U.S.C. § 112, first paragraph - enablement requirement

The Examiner's rejection is largely based on pre-filing date references showing that those skilled in the art expected that expression of a harpin under the control of a constitutive promoter in a transgenic plant cell would kill the cell. *See, e.g.*, Answer 5-6. The majority agrees with the Examiner that the prior art shows that "skilled artisans expected expression of hypersensitive response elicitor polypeptides with constitutive promoters would be lethal to plants, and therefore ineffective in protecting the plants against pathogens." (*Ante* at 14.)

I am not persuaded that the expectations of workers in the field is a sufficient basis for concluding that a claimed process is not enabled. Claims 41, 61, and 75 require, at most, the following experimental steps:

(1) Making a vector comprising one of SEQ ID NOs 1, 3, 5, or 7 operatively linked to a non-pathogen induced promoter functional in plants;

(2) Transforming plant cells with the vector;

(3) Growing the transgenic plant cells to generate a transgenic plant;

(4) Harvesting transgenic seeds from the transgenic plants;

(5) Planting the transgenic seeds; and

(6) Growing second-generation transgenic plants.

The evidence of record shows that each of these steps would have required no more than routine experimentation:

• the Specification itself discloses the structure of SEQ ID NOs 1, 3, 5, and 7 (Spec. 16-24);

• Takakura provides evidence that numerous non-pathogen-induced, plant-functional promoters were known in the art (Takakura 3-4, ¶¶ 23-26);

• the Examiner concedes that "plant transformation in general was well-known to those of skill in the art at the time of filing" (Answer 4-5); and

• the remaining experimental steps of growing plants and harvesting and planting seeds have been routine for millennia.

The basis of the Examiner's rejection, and the majority's affirmance of it, is that people skilled in the art would not have *expected* the disclosed process of making harpin-expressing transgenic plants to actually produce pathogen-resistant plants, as claimed. However, neither the Examiner nor the majority cites any evidence to support a finding that carrying out the required experimental steps would have entailed more than routine experimentation. Nor has the Examiner or the majority cited any evidence to show that anyone actually tried to make the transgenic plants described in the Specification and failed.

Evidence that the process described in the Specification was, in fact, enabled is provided in the Wei Declaration dated Aug. 11, 2004, which shows that expression of the *Erwinia amylovora* hrpN gene under control of the NOS promoter successfully creates pathogen-resistant transgenic plants. The majority discounts the Wei Declaration on the basis that it relies on "experimental methods and procedures not found or disclosed in the Specification" (*ante* at 15).

The majority does not, however, identify *which* experimental methods used in the Wei Declaration represent an advance in the art compared to what was disclosed in the instant Specification and known to those skilled in the art at the time it was filed. The Wei Declaration describes experiments

in which certain DNA constructs were made, plant cells were transformed with the constructs, plants were grown, and pathogen resistance was measured.

The constructs described in the Wei Declaration included the hrpN gene from *E. amylovora* (Wei Decl., ¶ 25), which was known in the art (Bauer, col. 2, ll. 31-40). The Wei Declaration provides citations for the NOS promoter and other regulatory sequences in the constructs that show they were known in the art (Wei Decl. ¶¶ 26, 27). The Examiner has stated that plant transformation was "well-known to those of skill in the art at the time of filing" (Answer 4-5).

The majority has not identified any product or process relied on by Dr. Wei that was not disclosed in the Specification or known to those skilled in the art at the time the instant application was filed. Thus, I disagree with the majority's conclusion that the Wei Declaration does not address the issue of enablement as of the filing date. In my view, the Wei Declaration confirms the Specification's statement that "various promoters" can be used to make the disclosed pathogen-resistant transgenic plants.

The Examiner's rejection for nonenablement is not supported by a preponderance of the evidence of record, and I would reverse it.

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